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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/555,099	11/02/2005	Celine Escoffier	279532US0PCT	9427
22850 7590 04/15/2009 OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER FERNANDEZ, SUSAN EMILY	
			ART UNIT	PAPER NUMBER
			1651	
			NOTIFICATION DATE	DELIVERY MODE
			04/15/2009	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/555,099	<b>Applicant(s)</b> ESCOFFIER ET AL.	
	<b>Examiner</b> SUSAN E. FERNANDEZ	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

The amendment filed December 22, 2008, has been received and entered.

Claim 27 is new. Claims 1-12 and 27 are pending and examined on the merits.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Montgomery (US 6,280,595, listed on 1/27/06 IDS).

Montgomery discloses a substrate comprising monomers, linker molecules, and pre-formed molecules, including nucleic acids, at a specific location which are proximate to an array of electrodes (column 11, lines 16-19 and column 12, lines 1-5). Note that column 12, lines 1-5 indicates that "...the substrate having one or more molecules bearing at least one protected chemical functional group bonded thereto **is proximate an array of electrodes...**" (emphasis added). Clearly a support (the substrate) is taught having an attachment zone (one or more molecules bearing at least one protected chemical functional group) that is not in direct contact with the electrodes which includes a working electrode. Therefore, there is a space separating the attachment zone and the working electrode.

An electric potential is applied to selected electrodes, where preferably each electrode is individually addressable and controllable by an electrical source (column 22, lines 12-15). Thus,

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a means for applying a given electric current or a give potential is present. Moreover, there can be a “getter” structure such as a second electrode proximate to the array of electrodes (column 6, lines 18-21). Since there are multiple electrodes, electrodes present may be a working electrode, a counterelectrode, or a reference electrode.

Claims 1, 2, 4, 5, and 12 are anticipated even though Montgomery does not specify that when the attachment zones and the electrodes are immersed in an aqueous solution, a local variation in pH in the region of the substrate (attachment zone) occurs, or that the reference electrode is placed so as to measure the potential applied to the working electrode (claim 5). There is anticipation since MPEP 2114 points out that "A claim containing a 'recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus' if the prior art apparatus teaches all the structural limitations of the claim." Note that column 17, lines 21-27 provides further support for compounds serving as probes on the substrate, including proteins, enzymes, nucleic acids, and antibodies, as required by instant claim 12.

Instant claim 3 is anticipated since Montgomery teaches that contemplated electrode array geometries include "concentric circle grid geometries wherein the electrodes form concentric circles about a common center" (column 22, lines 19-24). Claim 6 is anticipated because an electrode can be in any form (variety of sizes and shapes), thus the attachment zone is "...in the form of an electrode." Finally, claim 7 is anticipated since the molecules on the substrate (attachment zone) may be proteins, and proteins are known to be affected by pH.

A holding of anticipation is clearly required.

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Claims 1, 2, 4-7, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Ackley et al. (US 6,225,059).

Ackley et al. teaches devices for performing active biological operations to advantageously collect and provide charged biological materials to an array of microlocations (abstract). Figures 1A and 1B provides one embodiment of the device wherein individual electrodes 12 are covered by a permeation layer 14, above which are provided attachment regions 16 (column 12, lines 40-41, 51-53). The attachment regions 16 provide for specific binding sites for target materials (column 12, lines 52-53). The electrodes 12 can be activated to create lines of electrophoretic force 22 to cause transport of charged binding entities toward a positive electrode (column 13, lines 6-8). Electrodes 24 may be provided outside the array of electrodes 12 to serve as counterelectrodes (column 13, lines 15-18). Clearly Ackley et al. teaches a support comprising a surface comprising an attachment zone capable of being functionalized with a probe, a working electrode (at least one of electrodes 12), a counterelectrode (at least one of electrodes 24), a space separating the attachment zone and the working electrode (permeation layer 14), and a means for applying a given electric current or a given potential to the working electrode. Claims 1, 2, 4, 5, 6, and 12 are anticipated even though Ackley et al. does not specify that when the attachment zones and the electrodes are immersed in an aqueous solution, a local variation in pH in the region of the attachment zone occurs, or that the reference electrode is placed so as to measure the potential applied to the working electrode. There is anticipation since MPEP 2114 points out that "A claim containing a 'recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus' if the prior art apparatus teaches

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all the structural limitations of the claim.” Note that charged DNA are located within the reservoir 18 (column 12, lines 62-64), thus meeting limitations of claim 12.

Claim 7 is anticipated since the charged entities 20 can be charged DNA, and charged DNA are known to be affected by pH.

A holding of anticipation is clearly required.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-12 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Montgomery in view of Segev (US 5,843,650).

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As discussed above, Montgomery anticipates claims 1-7 and 12. However, Montgomery does not expressly disclose that the one or more molecules bearing at least one protected chemical functional group on the substrate are capable of binding to the monomers or pre-formed molecules so as to attach them by an electrophilic or nucleophilic group, such as an activated ester, or an amine, or that the one or more molecules on the substrate are chosen so that they can form with the monomers or pre-formed molecules a peptide bond.

Segev discloses a method and kit for detecting a target nucleic acid sequence which may be present in a test sample (column 5, lines 48-50). A pair of oligonucleotide probes is used, wherein one member of the pair has a nucleophilic chemical functionality group and the other pair has an electrophilic chemical functionality group (column 23, lines 46-50). The target molecule bonds with the oligonucleotide probes by chemical functionality groups (column 26, lines 20-24).

At the time the invention was made, it would have been obvious to the person of ordinary skill in the art to have used probes such as the oligonucleotide probes of Segev as the one or more molecules bearing at least one protected chemical functional group on the substrate of the Montgomery invention. One of ordinary skill in the art would have been motivated to do this since such oligonucleotide probes are suitable for the binding with nucleic acids, which are amongst the monomers or pre-formed molecules recited in Montgomery. Therefore, the one or more molecules bearing at least one protected chemical functional group on the substrate are capable of binding to the monomers or pre-formed molecules (when they are nucleic acids) so as to attach them by an electrophilic or nucleophilic group. It would have been obvious to have used activated ester or amine as the chemical functionality group of the one or more molecules

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on the substrate as they are known electrophilic/nucleophilic groups. Moreover, because of the different chemical functionality groups that may be used as oligonucleotide probes, it would have been obvious that different bonds, including peptide bonds, would have formed between the monomers or pre-formed molecules (nucleic acids) and the oligonucleotide probes used as the one or more molecules on the substrate of the Montgomery invention. Thus, claims 8-11 are rendered obvious.

Furthermore, Montgomery does not expressly disclose that the attachment zone (the one or more molecules bearing at least one protected chemical functional group) and the working electrode are coplanar. However, the arrangement of the working electrode relative to the attachment zone of the Montgomery invention would have been a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular arrangement was significant. Therefore, claim 27 is rendered obvious.

Thus, a holding of obviousness is clearly required.

Claims 1-12 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ackley et al. in view of Segev.

As discussed above, Ackley et al. anticipates claims 1, 2, 4-7, and 12. However, Ackley et al. does not expressly disclose that the functionalized specific binding entities 20 are capable of binding to targets so as to attach them by an electrophilic or nucleophilic group, such as an activated ester, or an amine, or that the one or more molecules on the substrate are chosen so that they can form with the monomers or pre-formed molecules a peptide bond.



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Segev discloses a method and kit for detecting a target nucleic acid sequence which may be present in a test sample (column 5, lines 48-50). A pair of oligonucleotide probes is used, wherein one member of the pair has a nucleophilic chemical functionality group and the other pair has an electrophilic chemical functionality group (column 23, lines 46-50). The target molecule bonds with the oligonucleotide probes by chemical functionality groups (column 26, lines 20-24).

At the time the invention was made, it would have been obvious to the person of ordinary skill in the art to have used probes such as the oligonucleotide probes of Segev as the functionalized specific binding entities of the Segev invention. One of ordinary skill in the art would have been motivated to do this since such oligonucleotide probes are suitable for the binding with nucleic acids. Therefore, there is attachment by an electrophilic or nucleophilic group. It would have been obvious to have used activated ester or amine as the chemical functionality group of the one or more molecules on the substrate as they are known electrophilic/nucleophilic groups. Moreover, because of the different chemical functionality groups that may be used as oligonucleotide probes, it would have been obvious that different bonds, including peptide bonds, would have formed between the monomers or pre-formed molecules (nucleic acids) and the oligonucleotide probes used as the functionalized specific binding entity 20 of the Segev invention. Thus, claims 8-11 are rendered obvious.

Furthermore, Segev et al. does not expressly disclose that the attachment layer and the working electrode are coplanar or in a design with the counterelectrode selected from the group consisting of an interdigitated comb design, a spiral design, and a concentric design. However, the arrangement of the working electrode relative to the attachment zone of the Segev invention

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would have been a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular arrangement was significant. Therefore, claims 3 and 27 are rendered obvious.

Thus, a holding of obviousness is clearly required.

### *Response to Arguments*

Applicant's arguments filed December 22, 2008, have been fully considered but they are not persuasive. The applicant argues that in the Montgomery device, the attachment zone is the working electrode. However, column 12, lines 1-5 indicates that "...the substrate having one or more molecules bearing at least one protected chemical functional group bonded thereto **is proximate an array of electrodes...**" (emphasis added). Clearly there is a space between the one or more molecules bearing at least one protected chemical functional group (the attachment zone) and the electrodes comprising a working electrode. The teaching in Montgomery that the working electrode is covered by a membrane containing reactive moieties is only one embodiment of the invention. Therefore, the claims under examination are anticipated by the Montgomery reference.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN E. FERNANDEZ whose telephone number is (571)272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/  
Primary Examiner, Art Unit 1651

Susan E. Fernandez  
Examiner  
Art Unit 1651

sef